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10/578,361	05/05/2006	Kuniaki Yamanaka	2006_0637A	6912

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WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER	
MALEKZADEH, SEYED MASOUD	
ART UNIT	PAPER NUMBER
1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,361	YAMANAKA ET AL.	
	Examiner	Art Unit	
	Seyed M. Malekzadeh	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-10,12-15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) *15 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-10,12-14,17-19 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims **5- 10, 12- 14, 17- 19, and 21- 26** stand **rejected**.

Claims **1- 4, 11, and 16** are **cancelled**.

Claims **15 and 20** are **withdrawn**.

Claims **21- 26** are **newly added** claims.

Claims **5- 10, 12- 13, 17- 19** are **amended**.

In view of the amendment, filed on 07/17/2009, following objections/rejections are **withdrawn** from the previous office action for the reason of record.

- Objection of specification
- Objection of claim 4
- Rejection of claims 4- 14 and 17- 19 under 35 U.S.C. 112, second paragraph
- Rejection of claims 4 and 11 under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 4,717,049)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 9- 10, 12- 13, 21- 22, and 25- 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al (US 4,717,049)

Green et al (US '049) teach an apparatus for producing uniform droplets of a liquid as a seamless capsule manufacturing device in which the forming apparatus comprises a capillary tube having a liquid receiving end and an open tip, means for supplying and controlling the flow of the liquid to the receiving end, an outer concentric tube having a converging-diverging venturi nozzle at the bottom in which the tip of the capillary tube being positioned in the throat of the venturi, a source of gas supplied to the outer tube, and means for regulating the flow of gas through said venturi nozzle to control the formation of droplets from the tip of the capillary tube. (See column 4 - lines 42- 55 and figure 2)

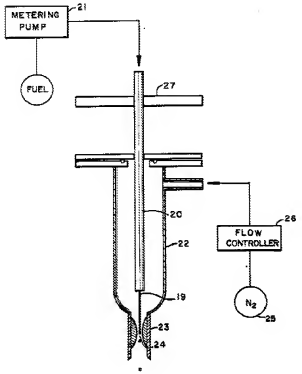

FIG. 2

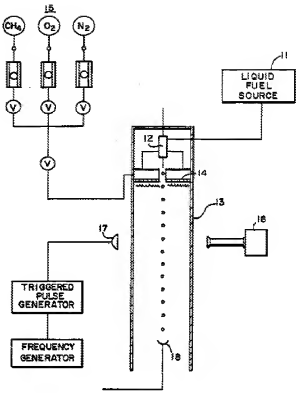

FIG. 1

Furthermore, Green et al (US '049) disclose the apparatus includes an outer concentric tube (22) with a venturi (23), both together, as a flow passage tube in which the flow passage tube includes an inlet part (22) and a deformation section (23), a tube (20) with the capillary tube (19) together as a nozzle received in the inlet part (22) in which a venturi (23) as a deformation section is connected at the bottom of the inlet part (22), and the deformation section (23) includes a smaller cross sectional area than the cross sectional area of the inlet part (22), and the diameter (D1) of the narrowest circle in the inner periphery of the deformation section (23) which is throat (23) is larger than the diameter of the capillary tube (19) or liquid drops and the diameter

(D2) of the inlet part (22) is larger than the diameter of the deformation section (23). (See column 4, lines 42- 55, column 2, lines 57- 68, column 3, lines 1- 20; and figure 2)

Also, Green et al (US '049) teach the metering pump (21) is connected to the tube (20) to provide fuel from the metering pump into the tube (20) and a flow controller (26) that regulates the flow of gas through the venturi (23) to control the formation of droplets from the tip of capillary tube (19).

Further, Green et al (US '049) disclose the Nitrogen gas from source (25) is supplied through flow controller (26) which regulates the flow of gas through the venturi (23) to control the formation of droplets from the tip of the capillary tube (19). By varying the liquid flow, gas flow, and capillary size the droplet size, spacing, frequency and initial velocity may be precisely controlled. (See column 3, lines 1- 6)

Thus, according to the Green et al (US '049), the deformation section (23) has a cross sectional area smaller than a cross sectional area of the inlet part of the inlet part (22) and controls formation of droplets from the tip of capillary tube (19) by varying the flow rate of the fluid within the venturi (23) in which results in controlling the size, spacing, frequency, and velocity of droplets.

Therefore, as to **claims 21, 25, and 26**, Green et al (US '049) teach a device comprises a nozzle (20) with a nozzle tip (19) for ejecting a liquid for forming capsules, a flow passage tube containing a fluid (22) wherein the flow passage tube (22) includes an inlet part and a deformation section (23) and the

deformation section (23) is arranged downstream of the inlet part of the flow passage tube (22) and the inlet part (22) is exposed to the nozzle for receiving the liquid ejected from the nozzle tip (19) and for forming the liquid drops, wherein the deformation section (23) has a cross sectional area smaller than a cross sectional area of the inlet part (22) for controlling the size, spacing, frequency, and velocity of droplets by varying the liquid flow or gas flow through flow controller (26), and the deformation section (23) includes an inner periphery such that a diameter of a largest circle which fits within the inner periphery of the deformation is larger than a diameter of the nozzle tip.

As to **claim 5**, Green et al (US '049) discloses the deformation section (23) is arranged **downstream** relative to the inlet part (22).

Also, Green et al (US '049) disclose the critical relationship between the size of the venturi throat and the diameter of the capillary tube will depend on the type of droplets to be produced. The capillary tube (19) has an inside diameter in the range of about 0.001" to 0.035" and an outside diameter of 0.005" to 0.05". The outer concentric tube (22) includes an inside diameter in the range of 0.1" to 2", and the throat of the venturi (23), as the deformation section includes an inside diameter in the range of 0.01" to 0.075" (See lines 29- 37, column 3); further, Green et al (US '049) teach a 32 gauge (0.004" inside diameter) stainless steel capillary was positioned in the throat of a venturi of approximately 1 mm inside diameter (See column 3, lines 23- 26). Thus, according to the teachings of the Green et al (US '049), when the

capillary includes an inside diameter of 0.004 inch, it is conferred that the diameter of the ejected droplet is also 0.004 inch and the above teachings satisfy the claims' requirements for **claims 9- 10, 12, and 22** in which the diameter D1, as the diameter of the largest circle in the inner periphery of the deformation section, is greater than the diameter D0, as the diameter of the ejected liquid drops and not greater than three times of the diameter D0 of the ejected liquid drops in the inlet part, and the diameter D1 is between one sixth times and two third times of the inner diameter D2 of the flow passage tube in the inlet part. Further, Green et al (US '049) teach the cross sectional area (S) of the deformation section is in a range of $(\pi/4)D_0^2 < S \leq (9\pi/4)D_0^2$ and the deformation section has a cross sectional area (S), wherein the inlet part has a cross sectional area (X), and wherein the flow passage is configured such that $(1/36)X<S<(4/9)X$ and also the cross sectional area (S) of the deformation section is between one thirty sixth times and four ninth times of the cross sectional area of the flow passage tube in the inlet part.

Furthermore, Green et al (US '049) teaches a method of producing uniform droplets of a liquid comprising supplying a stream of gas to a concentric tube, the stream of gas flowing through the concentric tube, supplying the liquid to a first end of a capillary tube as a part of the nozzle positioned in the concentric tube, and the step of passing the stream of uniform droplets through the inlet part (22) and the deformation section (23), (See column 2, lines 9- 25) Therefore, the prior art teaches a seamless capsule

manufacturing method characterized by manufacturing non-spherical seamless capsules by means of the disclosed seamless capsule manufacturing device.

The prior art, thus, meets all the claim limitations, and therefore, Green et al (US '049) anticipates the claims **5, 9- 10, 12- 13, 21- 22, and 25- 26.**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6- 8, 17- 19, and 23- 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (US '049) in view of Kosaka et al (US 5,209,978)

Green et al (US '049) teach all the structural limitations of a seamless capsule manufacturing device. **However**, Green et al (US '049) is **silent** about the shape of the cross section of the deformation section, as claimed in claims 6- 8 and 17- 19. Further, Green et al (US '049) **fail to teach** the tip portion of the nozzle is disposed above the inlet part of the flow passage tube, in such a way, that the deformation section receives the liquid drops from the inlet part, as claimed in claims 23- 24.

In the analogous art, Kosaka et al (US '978) teach a seamless capsule manufacturing device comprising a plurality of tanks (1- 4) for holding liquid substances for manufacturing soft capsules, a composite nozzle (5) as a duplex nozzle comprising outside nozzles (51 and 52) having a semielliptical cross sectional shape resulting from partitioning an elliptical tube by a portioning wall (50) at its center and inside nozzles (5a and 5b) of a smaller diameter disposed centrally in the outside nozzles (51 and 52), respectively in which the outside nozzles (51 and 52) communicate with the tanks 1 and 2, and the inside nozzles (5a and 5b) communicate with the tanks 3 and 4. The composite nozzle (5) faces downwardly along a downwardly flowing stream of a liquid medium within a capsule forming tank (6). (See column 2, lines 48- 68) Further, Kosaka et al (US 5,209,978) teach the droplets (f) formed by nozzle (5) enters a capsule forming tank (6) passing through a capsule recovery tube (61) to transfer the droplets (f) into a recovery hopper (7). (See column 3, lines 14- 17)

Therefore, Kosaka et al (US '978) disclose the cross section of the composite nozzle, as a tube member in the capsule manufacturing device which is in an elliptical or polygonal shape, and shows the cross section of the deformation section has a contour having at least one straight line. (See figures 2, 6, 10, and 8)

Further, Kosaka et al (US '978) teach the capsule forming tank (6) as a flow passage tube comprises an upper portion as an inlet part and a lower portion as a deformation section being arranged downstream of the inlet part, wherein the inlet part is exposed to the nozzle (5) so as to receive the liquid rejected from the nozzle (5) and to form the liquid drops, in such a way, that the nozzle (5) is disposed above the inlet part of the flow passage tube (6) and the flow passage tube (6) is disposed such that the deformation section receives the liquid drops from the inlet part.

It would have been obvious for one of ordinary skill in the art at the time of applicant's invention to modify the device as taught by Green et al (US '049) through providing a deformation section with an elliptic or polygonal shape or a cross section with a contour including one or more straight lines, as suggested Kosaka et al (US '978) since such a mere change in the shape of the apparatus member without affecting the functioning of the apparatus part would have been within the level of the ordinary skill in the art; also see *In re Dailey et al, 149 USPQ 47; Eskimo pie Corp. v, levous et al, 3 USPQ 23.*

Further, **it would have been obvious** for one of ordinary skill in the art at the time of applicant's invention to shift the location of the nozzle above the inlet part of the flow passage tube in such a way that the deformation section receives the liquid drops from the inlet part when the operation of the device is not otherwise changed since such a shifting is within the level of ordinary skill in the art, *In re Japikse*, 86 USPQ 70; *In re Gazda*, 104 USPQ 400.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (US '049) in view of Yeo et al. (US 2002/0160109)

Green et al. (US '049) teaches all the process steps of a seamless capsule manufacturing method as discussed above. **However,** Green et al. (US '049) **fail** to teach bringing the seamless capsules into contact with the ethanol type processing liquid, as claimed in claim 14.

In the analogous art, Yeo et al (US '109) teach a method for preparing an encapsulated composition through providing an aqueous solution composed of water and a core substance dissolved therein, providing a polymer solution composed of a water-miscible solvent and a water-insoluble polymer dissolved therein, forming a droplet of the aqueous solution containing the core substance, and admixing the droplet of aqueous solution with at least a portion of the polymer solution under conditions permitting the water-insoluble polymer to deposit as at least one layer on the core substance, wherein the aqueous solution includes a water-miscible solvent which is selected from the

group consisting of ethanol in which ethanol causes partial dehydrating the aqueous polymer solution, and concentrating the water soluble polymer in the water to form a polymer rich phase. (See paragraph [0017])

It would have been obvious for one of ordinary skill in the art at the time of applicant's invention to modify the process steps of a seamless capsule manufacturing method as taught by Green et al. (US '049) through bringing the seamless capsules into contact with the ethanol type processing liquid **in order to** dehydrate the aqueous polymer solution, and to increase the concentration of the soluble polymer in the water to form a polymer rich phase, as suggested by Yeo et al (US '109).

Examiner's Note

Claim 5 recites "where the ejected liquid drops arrive in a sol state" (See line 3), wherein the above recitation is the obtained product as a result of operating the claimed apparatus. Thus, the indicated limitation does not further provide patentable weight for the claimed apparatus itself. The claimed "ejected liquid drops" is the material or article the apparatus worked upon in which does not limit the apparatus claims. (See MPEP 2115[R- 2])

Claims **21, 25, and 26** recite "to contain a hardening liquid for hardening at least a surface part of liquid drops formed from the liquid ejected from said nozzle" (see lines 3- 4) and further recite "so as to deform each liquid drop to have an aspheric profile by changing a flow rate of the hardening liquid

to expand the liquid drop in a direction of a flow path of the hardening liquid" (see lines 10- 12) in which the recitation is directed to the manner or process of using the claimed deformation section and do not, further, provide any structural limitations for the claimed apparatus.

Thus, all the above recitations do not further limit the structure of the claimed apparatus and are directed to the structure of the claimed apparatus.

The manner or method in which a machine is to be utilized is not germane to the issue of patentability of the machine itself, *In re Casey*, 152 USPQ 235,238.

Purpose to which apparatus is to be put and expression relating apparatus to contents thereof during intended operation are not significant in determining patentability of an apparatus claim, *Ex parte Thibault*, 164 USPQ 666.

A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations, *EX parte Masham*, 2 USPQ2d 1647.

Response to Arguments

Applicant's **arguments** filed on 07/17/2009 have been fully considered but they are **not persuasive**.

Applicant **argues** that "thus even the structural requirements of claim 21 are not met by Green et al. reference. Claim 21 further sets forth functional limitations which are not met by the Green et al. reference. In particular, because Green et al. does not deform each liquid drop to have an aspheric profile by changing a flow rate of the hardening liquid to expand the liquid drop in a direction of a flow path of the hardening liquid, Green et al. can not meet the requirements of claim 21." (See remarks; page 18, lines 15- 20)

Applicant's **arguments** were fully considered but were **not found persuasive** because applicant's attention is drawn to the point that in process of patent examining a claimed apparatus, the patentable weight is only given to the claimed apparatus structure and no patentable weight is given to the process or manner of using the claimed apparatus; Green et al. meet all the structural limitations of the claims 5, 9- 10, 12- 13, 21- 22, and 25- 26, as discussed above in the body of the rejection. Further, in addressing the above arguments, Green et al clearly teach a venturi (23) as a deformation section (23) to control the formation of droplets from the tip of the capillary tube (19). Also, by varying the liquid flow, gas flow, and capillary size the droplet size, spacing, frequency and initial velocity may be precisely controlled. [See Green et al. (US '049); column 3, lines 1- 6] **Thus**, according to the Green et al (US '049), the deformation section (23) has a cross sectional area smaller than a cross sectional area of the inlet part (22) and controls formation of droplets from the tip of capillary tube (19) by varying the flow rate of the fluid within the

venturi (23) in which results in controlling the size, spacing, frequency, and velocity of droplets, which fulfill this claim limitation.

Further, cited limitations that "deformation section deforms each liquid drop to have an aspheric profile by changing a flow rate of the hardening liquid to expand the liquid drop in a direction of a flow path of the hardening liquid" is directed to the manner of using the claimed apparatus and do not give further patentable weight to the claimed apparatus; therefore, applicant's arguments in this regard in not on point.

Further, applicant's **arguments** that "The Kosaka and Yeo et al. references are relied upon in the office action for disclosures unrelated to the above-discussed deficiencies of Green et al" **were not found persuasive** because applicant's attention is drawn to the point that independent claims 21, 25- 26 have been anticipated by Green et al (US '049) and no reference has been combined with Green et al (US '049) to reject the independent claims. Thus applicant's arguments are not persuasive.

Therefore, the rejections of **claims 5- 10, 12- 15, 17- 26** are **maintained**.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Masoud Malekzadeh whose telephone number is 571-272-6215. The examiner can normally be reached on Monday – Friday at 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin, can be reached on (571) 272-1189. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance form a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Seyed M. Malekzadeh/

Examiner, Art Unit 1791

/Eric Hug/

Primary Examiner, Art Unit 1791